

HUTCHMED (13 HK)

FDA raised the bar for the approval of surufatinib

■ **FDA requires MRCT for the approval of surufatinib in the US.** The FDA has issued a Complete Response Letter (CRL) regarding the NDA of surufatinib for the treatment of extra-pancreatic and pancreatic neuroendocrine tumors (epNETs and pNETs). FDA decided that the current data package of two China Ph3 trials (SANET-ep and SANET-p) and one bridging study in the US (NCT02549937) does not support approval in the US. FDA requires an MRCT that includes subjects more representative of the US patient population and aligned to US medical practice, while FDA raised no concern on surufatinib's safety profile. Surufatinib received FDA Fast Track Designations in Apr 2020 for the treatment of pNETs and epNETs, and obtained Orphan Drug Designation for pNETs in Nov 2019. Considering the remarkable clinical efficacy of surufatinib demonstrated in the China Ph3 studies in NET, and the limited available therapies for NET in the US, we believe HCM will continue to pursue FDA approvals of surufatinib by conducting additional MRCTs. This FDA action may cause approximately 3-4 years of delay of surufatinib's US approval. Meanwhile, surufatinib's marketing application in the Europe is at the late stage of review, and the drug is undergoing a bridging study to support its application in Japan. We think the registration process of surufatinib in Europe and Japan should not be impacted by that in the US.

■ **Surufatinib to meet the large unmet need in NET treatment.** Surufatinib showed satisfying safety and potent efficacy for the treatment of NET. For the SANET-ep study, a Ph3 trial in advanced epNET patients in China, median PFS was significantly longer for surufatinib arm at 9.2 months, compared to 3.8 months for placebo arm (HR 0.334; $p < 0.0001$). For the SANET-p study, a Ph3 trial in advanced pNET patients in China, surufatinib achieved a median PFS of 10.9 months vs 3.7 months for placebo (HR 0.491; $p = 0.0011$). In the US phase 1/2 bridging study ([link](#)), surufatinib's mPFS was 11.50 months and 15.18 months for patients with epNETs and pNETs, respectively. Currently, there's limited targeted therapies for NETs in China and the US, mainly sunitinib for pNET and everolimus for pNET and non-functional NET of GI or lung origin. Thus, we see large global market potential for surufatinib as a potent targeted therapy for NET.

■ **Ongoing MRCTs of other key assets form the basis for HCM's global expansion.** The ongoing global phase 2 SAVANNAH trial of savolitinib for NSCLC and the global phase 3 FRESCO-2 trial of fruquintinib for colorectal cancer are expected to have data read-out within this year, based on which HCM may file applications in the US and other global markets.

■ **Maintain BUY.** We revised our DCF-based TP from HK\$73.25 to HK\$51.15 based on a 14-year DCF valuation (WACC: 10.47%, terminal growth rate: 3%).

Earnings Summary

(YE 31 Dec)	FY20A	FY21A	FY22E	FY23E	FY24E
Revenue (US\$ mn)	228	356	443	552	841
YoY growth (%)	11	56	24	25	52
Net loss (US\$ mn)	(126)	(195)	(325)	(281)	(111)
EPS (US\$)	(0.18)	(0.25)	(0.38)	(0.33)	(0.13)
Consensus EPS (US\$)	N/A	N/A	(0.45)	(0.42)	(0.25)
R&D expenses (US\$ mn)	(175)	(299)	(330)	(350)	(336)
Capex (US\$ mn)	(8)	(16)	(50)	(15)	(10)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	HK\$51.15
(Previous TP)	HK\$73.25)
Up/Downside	+141.83%
Current Price	HK\$21.15

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Mkt. Cap. (HK\$ mn)	18,285
Avg. 3mths t/o (HK\$ mn)	30.58
52W High/Low (HK\$)	85.80/20.75
Total Issued Shares (mn)	865

Source: Bloomberg

Shareholding Structure

CK Hutchison Holdings	38.46%
The Capital Group	10.79%
JP Morgan	6.21%
Free float	44.54%

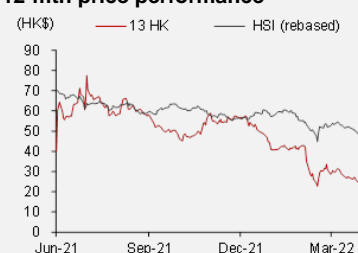
Source: HKEx, Bloomberg

Share performance

	Absolute	Relative
1-mth	-13.2%	-9.3%
3-mth	-37.0%	-28.9%
6-mth	-46.3%	-36.1%

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: PricewaterhouseCoopers
Web-site: <https://www.hutch-med.com>

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Figure 1: Risk-adjusted DCF valuation

DCF Valuation (in US\$ mn)	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	(217)	(330)	(287)	(115)	147	316	517	714	910	1,014	1,077	1,121	1,008	1,031	1,055
Tax rate	-6%	0%	0%	0%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	(229)	(330)	(287)	(115)	125	268	440	607	774	862	916	953	857	876	896
+ D&A	7	8	17	16	15	14	13	13	12	12	11	11	11	11	11
- Change in working capital	33	21	(11)	(24)	(50)	(74)	(58)	(62)	(49)	(39)	(29)	(19)	(4)	32	(7)
- Capex	(16)	(50)	(15)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
FCFF	(206)	(351)	(296)	(133)	80	199	384	548	727	824	888	935	853	908	889
Terminal value															12,265
Present value of enterprise (US\$ mn)	5,076														
Net debt (US\$ mn)	(630)														
Equity value (US\$ mn)	5,706														
Equity value (HK\$ mn)	44,218														
No. of outstanding shares (mn)	865														
DCF per share (HK\$)	51.15														
Terminal growth rate	3.0%														
WACC	10.47%														
Cost of Equity	13.5%														
Cost of Debt	4.0%														
Equity Beta	1.00														
Risk Free Rate	3.0%														
Market Risk Premium	10.5%														
Target Debt to Asset ratio	30.0%														
Effective Corporate Tax Rate	15.0%														

Source: CMBIGM estimates

Figure 2: Sensitivity analysis (HK\$)

		WACC				
		9.47%	9.97%	10.47%	10.97%	11.47%
Terminal growth rate	4.00%	68.70	61.62	55.67	50.60	46.25
	3.50%	64.94	58.62	53.25	48.62	44.61
	3.00%	61.75	56.05	51.15	46.89	43.17
	2.50%	59.03	53.82	49.31	45.37	41.90
	2.00%	56.66	51.88	47.69	44.01	40.75

Source: CMBIGM estimates

Figure 3: CMBIGM estimates revision

US\$ mn	New			Old			Diff (%)		
	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E
Revenue	443	552	841	454	620	974	-2%	-11%	-14%
Gross Profit	128	199	387	134	240	474	-4%	-17%	-18%
Operating Profit	(330)	(287)	(115)	(326)	(252)	(108)	N/A	N/A	N/A
Net profit	(325)	(281)	(111)	(320)	(247)	(103)	N/A	N/A	N/A
EPS (US\$)	(0.38)	(0.33)	(0.13)	(0.37)	(0.29)	(0.12)	N/A	N/A	N/A
Gross Margin	28.88%	35.96%	46.08%	29.52%	38.71%	52.82%	-0.63 ppt	-2.75 ppt	-6.75 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Figure 4: CMBIGM estimates vs consensus

US\$ mn	CMBIGM			Consensus			Diff (%)		
	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E	FY22E	FY23E	FY24E
Revenue	443	552	841	419	544	804	6%	1%	5%
Gross profit	128	199	387	148	239	415	-13%	-17%	-7%
Operating profit	(330)	(287)	(115)	(392)	(373)	(249)	N/A	N/A	N/A
Net profit	(325)	(281)	(111)	(358)	(320)	(196)	N/A	N/A	N/A
EPS (US\$)	(0.38)	(0.33)	(0.13)	(0.45)	(0.42)	(0.25)	N/A	N/A	N/A
Gross margin	28.88%	35.96%	46.08%	35.24%	44.00%	51.66%	-6.35 ppt	-8.04 ppt	-5.58 ppt

Source: Bloomberg, CMBIGM estimates

Financial Statements

Income statement

YE 31 Dec (US\$ mn)	FY20A	FY21A	FY22E	FY23E	FY24E
Revenue	228	356	443	552	841
COGS	(189)	(258)	(315)	(353)	(453)
Gross profit	39	98	128	199	387
Administrative expenses	(50)	(89)	(75)	(80)	(84)
R&D expenses	(175)	(299)	(330)	(350)	(336)
Selling expenses	(11)	(38)	(53)	(55)	(82)
Operating profit	(197)	(328)	(330)	(287)	(115)
Gain on divestment equity investee	0	121	0	0	0
Interest income	3	2	4	3	3
Other income (expenses), net	5	2	0	0	0
Interest expense	(1)	(1)	(0)	(0)	(0)
Other expense	(0)	(13)	0	0	0
Pre-tax profit	(190)	(216)	(327)	(284)	(113)
Income tax	(5)	(12)	0	0	0
Equity in earnings of equity investees, net of tax	79	61	30	30	30
Minority interests	(10)	(28)	(28)	(28)	(28)
Net profit (loss)	(126)	(195)	(325)	(281)	(111)

Cash flow summary

YE 31 Dec (US\$ mn)	FY20A	FY21A	FY22E	FY23E	FY24E
Profit before tax	(116)	(167)	(297)	(254)	(83)
Depreciation and amortization	6	7	8	17	16
Change in working capital	29	33	21	(11)	(24)
Changes in income tax balances	(1)	7	0	0	0
Others	19	(84)	(30)	(30)	(30)
Net cash from operating activities	(62)	(204)	(298)	(278)	(121)
Capex	(8)	(16)	(50)	(15)	(10)
Net proceeds from disposal of short-term investments	(733)	(1,356)	0	0	0
Other investing activities	615	1,066	300	300	0
Net cash from investing activities	(125)	(306)	250	285	(10)
Net proceeds from shares issued	319	717	0	0	0
Net bank borrowing	0	0	0	0	0
Other financing activities	(23)	(67)	0	0	0
Net cash from financing activities	296	650	0	0	0
FX changes	6	2	0	0	0
Net change in cash	109	139	(48)	7	(131)
Cash at the beginning of the year	121	236	378	330	337
Cash at the end of the year	236	378	330	337	206

Balance sheet

YE 31 Dec (US\$ mn)	FY20A	FY21A	FY22E	FY23E	FY24E
Non-current assets	193	161	232	261	284
PP&E	24	41	83	81	75
Right-of-use assets	8	12	12	12	12
Deferred tax assets	2	9	9	9	9
Investments in equity investees	0	0	0	0	0
Other non-current assets	20	22	22	22	22
Current assets	531	1,212	841	568	467
Cash and cash equivalents	236	378	330	337	206
Short-term investments	200	634	334	34	34
Accounts receivable	48	84	66	82	102
Inventories	20	36	30	34	43
Other current assets	28	81	81	81	81
Current liabilities	158	312	309	318	324
Accounts payable	32	41	39	48	53
Other payables, accruals and advance receipts	121	211	211	211	211
Lease liabilities	3	0	0	0	0
Other current liabilities	(1)	55	31	31	31
Non-current liabilities	47	21	21	21	21
Lease liabilities	6	7	7	7	7
Long-term bank borrowings	27	0	0	0	0
Other non-current liabilities	14	14	14	14	14
Total net assets	519	1,040	743	489	406
Minority interest	35	53	80	108	135
Shareholders' equity	484	987	662	381	271

Key ratios

YE 31 Dec	FY20A	FY21A	FY22E	FY23E	FY24E
Profit & loss ratios (%)					
Gross margin	17	27	29	36	46
EBITDA margin	N/A	N/A	N/A	N/A	N/A
Net margin	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	N/A	N/A	N/A	N/A	N/A
Balance sheet ratios					
Current ratio (x)	3	4	3	2	1
Inventory days	35	39	35	35	35
Account receivables turnover days-third parties	70	66	66	66	66
Account receivables turnover days-related parties	2	1	1	1	1
Account payables turnover days	54	51	55	55	55
Total debt to asset ratio (%)	28	24	31	41	46
Returns (%)					
ROE	(22)	(16)	(40)	(52)	(20)
ROA	(16)	(12)	(28)	(31)	(11)
Per share data					
EPS (US\$)	(0.2)	(0.2)	(0.4)	(0.3)	(0.1)
DPS (US\$)	0.0	0.0	0.0	0.0	0.0
BVPS (US\$)	0.7	1.3	0.9	0.6	0.5

Source: Company data, CMBIGM estimates

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